



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: SENSOR PAD®
Docket No. 97E-0069

JUL - 8 1997

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
U.S. Patent and Trademark Office
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

RECEIVED
JUL 16 1997
PATENT EXTENSION
A/C PATENTS

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. Re. 34,353 filed by Inventive Products, Inc., under 35 U.S.C. § 156. The medical device claimed by the patent is SENSOR PAD®.

A review of the Food and Drug Administration's official records does not confirm that SENSOR PAD® was subject to a regulatory review period as it is defined in 35 U.S.C. § 156. For medical devices, section 156(g)(3) limits the meaning of the term "regulatory review period," to periods of time related to product approvals under section 515 of the Federal Food, Drug, and Cosmetic Act (FFDCA). SENSOR PAD® was not approved under section 515, but instead received clearance to market under section 510(k) of the FFDCA.

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A), we will then determine the applicable regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Philip L. Bateman, Esq.
555 South Seigal Street
P.O. Box 1105
Decatur, IL 62525